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|-----------------|-------------|----------------------|---------------------|------------------|
| 10/542,810      | 03/01/2006  | Masaaki Uenaka       | SHIOP0100US         | 8381             |

7590 11/03/2009  
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| EXAMINER |
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BERCH, MARK L

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| ART UNIT | PAPER NUMBER |
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1624

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11/03/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/542,810 | <b>Applicant(s)</b><br>UENAKA, MASA AKI |  |
|                              | <b>Examiner</b><br>Mark L. Berch     | <b>Art Unit</b><br>1624                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09/16/2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 1-propanol, does not reasonably provide enablement for other solvents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Example 7 used 2-pentanol, and example 8 has 1-pentanol and example 9 has t-amyl alcohol and example 10 has 1-propanol. But the actual products are solvates of both water and the alcohol. Such compounds do not fall within claim 1. That is, while one might have expected a solvate of 1-pentanol from example 7, in fact, the product is listed as a hydrate-solvate, and thus, applicants have not shown that a straight solvate with 1-pentanol can be formed.

The traverse is unpersuasive. It does not come to terms with the problem here. The examiner understands that hydrates are a type of solvate. The problem is that claim 1 reads on the solvate with e.g. t-amyl alcohol. However, the actual product obtained was not

Art Unit: 1624

the solvate of t-amyl alcohol, it was the solvate of t-amyl alcohol and water both. Applicants have not demonstrated that the compound forms a solvate with just t-amyl alcohol, and indeed, the evidence is that it does not, since that product was not reported. The solvate of t-amyl alcohol and water both does not fall within claim 1, in part because water is not on the list of solvents in claim 1. Thus, while applicants state, "Applicants have provided more than enough information to enable the invention claimed", this is not true, since the information provided tends to show that compound which applicants claim does not exist, or at least, is not formed in the process which applicants teach.

Claims 7-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

See preceding rejection. The compounds of claims 7, 9, 11, and 13 are not described correctly. These are actually solvate hydrates, not just solvates. Changing the name would fix the problem.

The traverse is unpersuasive. Applicants note that claim 1 has been amended, which did indeed take care of some rejections, but that did not deal with this point. The remarks state, "the term "solvates" includes compounds having water and/or another solvent adsorbed on the solute." That is correct, but does not go to the issue here. The actual compound is not just a 2-pentanol solvate, it is a 2-pentanol solvate hydrate. The claim names one of the solvating molecules, but not the other. The name is just as incorrect as it would be if it were called a water hydrate. The name must indicate everything that is there, not just some of it. The actual species is a solvate of two solvents and therefore, both of the two solvents must be named.

Art Unit: 1624

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compound or crystal, does not reasonably provide enablement for the solvate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicants have shown that the esters form solvates, at least with some alcohols. However, applicants have not shown that Formula II, which is an acid, forms the hydrate of claim 19.

The traverse is unpersuasive. Applicants point to their 10 examples --- but where is an example of a hydrate of the acid?

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amendment to the claim is unclear. It is not clear from this whether the “solvate” is a required feature or an alternative. Does not claim cover the non-solvate or not? If yes, then “or” belongs before “a solvate”. If no, then “a solvate of” should appear after “producing”.

### *Specification*

Examples 7-10 of the specification are objected to. These examples appear to be defective. The compounds are listed as being hydrates, and yet water was not used. For example, the analysis for example 7 lists the compound as having 2 ½ moles of water per mole of the  $\beta$ -lactam. Where did all this water come from? Note that compound (I) is not listed as being a hydrate.

Art Unit: 1624

The traverse is unpersuasive. Applicants say that the source of water “may be the amorphous powder of the compound (I)”. Simply raising a possibility is not an answer at all. Further, this answer seems unlikely. It is not called a hydrate --- this in the context of a specification where other things are called hydrates. Since things which are hydrates are called hydrates, the fact that (I) is not called a hydrate indicates that it likely is not. Moreover, the PMR of (I) (see reference example 1) makes no allusion of (I) being a hydrate.

Applicants also refer to “impurities” in the solvent. This is entirely speculative. Ordinary alcohol solvents have only tiny traces of water --- but these have substantial amounts of water --- ranging from 1.5 moles to 3.5 moles of water per mole of product!

Finally, applicants refer to water absorbed from the environment. Again, this is entirely speculative. In fact, there is no mention of any compounds being hygroscopic.

If applicants believe that the experiments are not defective, they must determine where the water comes from, and present some sort of evidence that this is just a guess. As the spec presently stands, it does not make sense.

### ***Claim Objections***

Claims 7-14 are improperly dependent on claim 1, which does not provide for hydrates, which, according to the specification, is what these materials really are.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed

Art Unit: 1624

until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark L. Berch/  
Primary Examiner  
Art Unit 1624

Application/Control Number: 10/542,810

Page 7

Art Unit: 1624

11/3/2009